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EXAMINER
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SMITH, TERRI L

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 09/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/667,206

Applicant(s)

TERNES, DAVID

Examiner

Terri L. Smith

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 22 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-80 is/are pending in the application.
- 4a) Of the above claim(s) 1-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 38-80 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1–37, drawn to a method, classified in class 607, subclass 27.

II. Claims 38–80, drawn to a system, classified in class 607, subclass 32.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions of Group I (process) and Group II (apparatus) are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus as claimed can be used to practice another and materially different process not requiring a memory storage circuit for storing data, but reading the data in real-time for a one time use and discarding the data thereafter.

3. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the Examiner if restriction is not required because the inventions have acquired a separate status in the art due to their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

4. During a telephone conversation with Timothy E. Bianchi on Monday, September 11, 2006 a provisional election was made without traverse to prosecute the invention of Group II, claims 38–80. Affirmation of this election must be made by Applicant in replying to this Office Action. Claims 1–37 are withdrawn from further consideration by the Examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

***Claim Objections***

5. Claims 38 and 72 are objected to because of the following informalities: In line 2 of claims 38 and 72, the last word “a” should be the word “an” instead. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the Applicant regards as his invention.

7. Claim 54 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. In claim 54, the phrase “an elevated value of the resting heart rate” is confusing. It is unclear how a resting heart rate can have an elevated value in and of itself. One of ordinary skill in the art would deem a resting heart rate to be a given value. If that given value is elevated, it is no longer a resting heart rate; the person has to be doing something other than resting to cause the heart rate to elevate.

***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 38, 39, 40, 42, 49, 50, 51, 52, 55, 56, 62, 64, 65, 68, and 71–74, 76, 80 are rejected under 35 U.S.C. 102(b) as being anticipated by Dardik, U.S. Patent 5,163,439.

10. Regarding claims 38 and 72, Dardik discloses a processor circuit (column 6, lines 65–68), including at least one predetermined criteria to identify a exercise episode of a patient (column 5, lines 20–24; column 8, lines 29–32), and including data input to receive data associated with an episode (Fig. 1; column 4, lines 19–27); a memory storage (column 4, lines 54–61); and an external display/means for displaying (Fig. 1, element 13), including a displayed summary of an episode (Fig. 2), a summary including at least one displayed prognostic indicator obtained from the data associated with an episode (column 5, lines 43–47).

11. Dardik discloses an episode includes an exercise period and a post-exercise recovery period (claims 39 and 73) (column 5, lines 24–25 and 29–33); data input receives heart rate data (12, heart beat monitor), and in which at least one predetermined criteria includes at least one heart rate threshold that defines an episode for heart rates substantially continuously exceeding the at least one heart rate threshold (claims 40 and 74) (Fig. 2; column 5, lines 43–47, wherein Examiner considers the lower limit heart beat of 130 as the equivalent to the claimed limitation of at least one heart rate threshold that is being substantially continuously exceeded); a processor includes a user-input to receive at least one user-provided trigger identifying an episode (claims 42 and 76) (column 7, lines 13–20 wherein Examiner considers the identifying episode as limit adjustment mode or a time period adjustment mode); at least one displayed prognostic indicator includes an indication of a rate of decrease of a patient's heart rate during a post-exercise recovery portion of the episode (claims 49 and 80) (column 5, lines 29–32); at least one displayed prognostic indicator includes an indication of a maximum heart rate obtained by a patient during an episode (claim 50) (Fig. 2, 160 heart rate); at least one displayed prognostic indicator includes an indication of an age-predicted maximum heart rate for a patient for

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comparison to an indication of a maximum heart rate obtained by a patient during an episode (claim 51) (Fig. 2; column 5, lines 20–24); at least one displayed prognostic indicator includes an indication of a comparison between a maximum heart rate obtained by a patient during an episode and an indication of an age-predicted maximum heart rate for a patient (claim 52) (Fig. 2); at least one prognostic indicator includes an indication of heart rate variability associated with an episode (claim 55) (Fig. 2); at least one prognostic indicator indicates a low heart rate variability (claim 56) (Fig. 2, where Examiner considers the heart rate values between 90 and approximately 129 to be low heart rate variability because the rates are below the patient's established lower heart rate limit of 130); a displayed summary includes a displayed graph of heart rate vs. time during at least a portion of an episode (claim 62) (Fig. 2); a graph includes an indication of an age-predicted maximum heart rate for a patient (claim 64) (Fig. 2; column 5, lines 20–24); a graph includes a first indicator of at least one exercise period during an episode (claim 65) (Fig. 2; column 5, lines 43–47); a summary includes a displayed graph of patient activity vs. time during an episode (claim 68) (Fig. 2 where Examiner interprets change of heart rate to be indicative of patient activity); a processor is located in an external device (claim 71) (column 6, lines 65–68).

12. Claims 38, and 72 are rejected under 35 U.S.C. 102(b) as being anticipated by Heikkilä, U.S. Patent 5,840,039.

13. Regarding claims 38 and 72, Heikkilä discloses a processor circuit (Fig. 3), including at least one predetermined criteria to identify a exercise episode of a patient (column 3, lines 56–58; column 4, lines 1–8), and including a data input circuit to receive data associated with an

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episode (Fig. 3); a memory storage circuit (Fig. 3, element 9, memory), coupled to a data input circuit to store the data (Fig. 3); and an external display (10), including a displayed summary of an episode (column 3, lines 56–58), a summary including at least one displayed prognostic indicator obtained from the data associated with an episode (column 3, lines 56–62; column 4, lines 27–37).

***Claim Rejections - 35 USC § 103***

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. Claims 41 and 75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heikkilä, U.S. Patent 5,840,039 as applied to claims 38 and 72 above, and in view of Alexander et al., U.S. Patent 5,243,993.

16. Heikkilä discloses a data input circuit receives activity sensor data (Fig. 3) but not at least one predetermined criteria includes at least one activity sensor threshold that defines an episode for activity sensor levels that substantially continuously exceed an activity sensor threshold. However, Alexander et al. disclose one predetermined criteria includes at least one activity sensor threshold that defines an episode for activity sensor levels that substantially continuously exceed an activity sensor threshold (Fig. 11) to ensure the most accurate heart rate reading for use in determining the patient's optimum safety range during heart rate monitoring while exercising. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Heikkilä to include one predetermined

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criteria includes at least one activity sensor threshold that defines an episode for activity sensor levels that substantially continuously exceed an activity sensor threshold, as taught by Alexander et al. to ensure optimum patient safety.

17. Claims 43 and 77 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heikkilä, U.S. Patent 5,840,039 as applied to claims 38, 62 and 72 above, and in view of Gamlyn et al., U.S. Patent 5,749,367.

18. Regarding claims 43 and 77, Heikkilä discloses the essential features of the claimed invention as described above except for at least one displayed prognostic indicator includes an indication of how many ectopic beats occurred during an episode. However, Gamlyn et al. disclose at least one displayed prognostic indicator includes an indication of how many ectopic beats occurred during an episode (column 19, lines 27–29) to provide an accurate indication of heart stress in a patient who is engaged in exercise and provide accurate data for analysis by a medical care provider. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Heikkilä to include at least one displayed prognostic indicator includes an indication of how many ectopic beats occurred during an episode as taught by Gamlyn et al. to provide an accurate indication of heart stress in a patient who is engaged in exercise and provide accurate data for analysis by a medical care provider.

19. Claims 53, 54, 57–61, 66, 67, 69, and 70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heikkilä, U.S. Patent 5,840,039.



20. Heikkilä discloses the essential features of the claimed invention as described above except for at least one displayed prognostic indicator includes a resting heart rate associated with an episode (claim 53), QT dispersion associated with the episode (claim 60), paroxysmal atrial tachyarrhythmia associated with the episode (claim 61); at least one prognostic indicator indicates an elevated value of a resting heart rate (claim 54); at least one prognostic indicator includes an indication of T-wave alternans associated with an episode (claim 57), a heart rate corresponding to an onset of a T-wave alternans associated with an episode (claim 58) and heart rate turbulence associated with an episode (claim 59), and a second indicator of at least one post-exercise refractory period during the episode (claim 66) and a displayed heart electrical activity signal associated with an episode (claim 69). However, it is well known in the art that the accurate measurement of heartbeat rate and related phenomena, and unambiguous timing points of each ECG signal obtained from QRS complexes, such as at least one displayed prognostic indicator includes a resting heart rate associated with an episode, QT dispersion associated with the episode, paroxysmal atrial tachyarrhythmia associated with the episode; at least one prognostic indicator indicates an elevated value of a resting heart rate; at least one prognostic indicator includes an indication of T-wave alternans associated with an episode, a heart rate corresponding to an onset of a T-wave alternans associated with an episode and heart rate turbulence associated with an episode, and a second indicator of at least one post-exercise refractory period during the episode and a displayed heart electrical activity signal associated with an episode, are used to determine the stress, relaxation and overall condition of a patient while monitoring heart rate during and after exercise and displayed for analysis by a medical care provider. Therefore, it would have been obvious to one of ordinary skill in the art at the

time the invention was made to have modified the invention of Heikkilä to include at least one displayed prognostic indicator includes a resting heart rate associated with an episode, QT dispersion associated with the episode, paroxysmal atrial tachyarrhythmia associated with the episode; at least one prognostic indicator indicates an elevated value of a resting heart rate; at least one prognostic indicator includes an indication of T-wave alternans associated with an episode, a heart rate corresponding to an onset of a T-wave alternans associated with an episode and heart rate turbulence associated with an episode, and a second indicator of at least one post-exercise refractory period during the episode and a displayed heart electrical activity signal associated with an episode to diversify, enhance and improve system function and capability to monitor a patient's heart rate while the patient is exercising.

21. With respect to claim 67, Heikkilä discloses the essential features of the claimed invention as described above except for first and second indicators include different background colors. However, it would have been an obvious matter of design choice to a person of ordinary skill in the art at the time the invention was made to modify the invention of Heikkilä to include first and second indicators include different background colors to make it easier to differentiate, read and analyze data on a display. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Heikkilä to include first and second indicators include different background colors to provide an enhanced user-friendly display.

22. Regarding claim 70, Heikkilä discloses the essential features of the claimed invention as described above except for a processor is located in an implantable device. However, it is well known in the art for a processor to be located in an implantable device so that the patient is not

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hindered or impeded in any way while exercising and undergoing heart rate monitoring.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Heikkilä to include a processor located in an implantable device to provide comfort to the patient and ease of data collection for the exercise monitoring system.

***Allowable Subject Matter***

23. Claims 44, 45, 46, 47, 48, 63, 78, and 79 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Conclusion***

24. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Terri L. Smith whose telephone number is 571-272-7146. The Examiner can normally be reached on Monday - Friday, between 7:30 a.m. - 4:00 p.m..

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



TLS

September 14, 2006

14 September 2006



GEORGE R. EVANISKO  
PRIMARY EXAMINER

9/15/06